

EXHIBIT J

Steptoe & Johnson LLP
227 West Monroe Street, Suite 4700
Chicago, IL 60606
312 577-1300 main
www.steptoelaw.com

October 25, 2021

VIA E-MAIL

Kia Freeman, Esq.
McCarter & English, LLP
265 Franklin Street
Boston, MA 02110

**Re: Aquestive v. BDSI | Case No. 19-cv-00505-D (E.D.N.C.)
Indivior et. al. v. BDSI | Case No. 5:15-CV-350-D (E.D.N.C.)
BDSI's Responses to First Set of RFP Nos. 1-12**

Dear Ms. Freeman:

I am writing regarding BDSI's responses to Plaintiff(s)'s First Set of Requests for Production ("RFPs") received on June 7, 2021 and BDSI's document production in the above captioned cases. As a general matter and as described in more detail below, BDSI's responses are deficient at least because BDSI's responses and objections do not comply with FRCP 34 and BDSI's document production remains deficient. While this letter addresses specific deficiencies with respect to specific responses to Plaintiff(s)'s RFPs, this letter should not be taken as an indication or admission that any of the remaining responses, or parts thereof, are adequate. Plaintiffs reserve the right to challenge the sufficiency of the remaining responses, or parts thereof, at an appropriate time.

1. BDSI failed to identify whether it is withholding any documents on the basis of its objections.

BDSI asserts fourteen paragraphs of "General Objections," as well as a boilerplate privilege objection with respect to each RFP (Nos. 1-12). With respect to privilege, again for each RFP, BDSI states that "BioDelivery objects to this Request as seeking the production of information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity."

BDSI notes that its responses to each RFP (Nos. 1-12) are subject to these objections. For example, for its response to RFP No. 1, BDSI states: "Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged

documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.” However, BDSI fails to indicate whether BDSI is withholding any responsive documents on the basis of these objections.

Please supplement BDSI’s responses to each of Plaintiff(s)’s RFP Nos. 1-12 no later than 14 days from the date of this letter, indicating whether BDSI is withholding any relevant documents on the basis of any of its objections, and identifying with specificity which objections form the basis for BDSI’s withholding. To the extent BDSI is **actually** withholding any documents on the basis of privilege, please also confirm that BDSI will produce a corresponding privilege log indicating the nature of the asserted privilege and the information specified in Paragraph 7 of the Instructions to Plaintiff(s)’ First Set of RFPs to BDSI.

2. BDSI’s offer to meet-and-confer is not an excuse for failure to produce relevant and responsive documents (RFP Nos. 5-7, 11).

With respect to RFP Nos. 5-7, and 11 BDSI repeats its boilerplate objections (*see* Section 1, *supra*) and offers to meet and confer instead. BDSI does not explain why it is unable to produce any documents and did not explain why it contends that each of the requests is “vastly overbroad, unduly burdensome, and not proportional to the needs of this case.” BDSI should produce relevant and responsive documents as soon as practicable and no later than 14 days from the date of this letter.

3. BDSI’s production of documents to date remains deficient (RFP Nos. 1-12).

Review of over 8,000 documents produced by BDSI across both cases, including the metadata accompanying BDSI’s production, indicates that BDSI limited its production to documents submitted to the FDA. While RFP Nos. 1 and 8 specifically call for documents that were submitted to the FDA by BDSI, on BDSI’s behalf, or for BDSI’s benefit, the remaining RFPs clearly do not (No. 2-7, 9-12). To the extent BDSI disagrees with the evaluation regarding the scope of its production, please so state and please provide **all** BATES ranges of documents that BDSI asserts are not part of FDA submissions made by BDSI, on BDSI’s behalf or for BDSI’s benefit.

With respect to RFP Nos. 1 and 8, please indicate whether BDSI’s production is complete.

Furthermore, with respect to the remaining RFPs Nos. 2-7, and 9-12, BDSI does not appear to have produced any responsive documents. With respect to RFP Nos. 5-7, and 11, that failure seems to be tied to BDSI’s meet-and-confer request made improperly *in lieu* of production. *See* Section 2, *supra*. With respect to RFP Nos. 2-3, and 12, however, BDSI has

failed to provide responsive documents that are not otherwise covered by the specific FDA submission request (RFP Nos. 1 and 8). These requests clearly call for documents that were not part of the submission:

*RFP No. 2: "All documents and things considered or relied upon by Defendant **in preparation** of Defendant's NDA and any amendments or supplements thereof."*

*RFP No. 3: "All documents and things concerning any correspondence or communication relating to Defendant's NDA and/or BELBUCA, **including** any and all correspondence or communications to or from the FDA concerning Defendant's NDA, including any and all NDA amendments and supplements."*

*RFP No. 12: "All documents and things relating to Defendant's **assertions** that Defendant's BELBUCA Product does not infringe and will not infringe the patents-in-suit, including all such information that Defendant contend support those positions or which tends to undermine or contradict such contentions."*

Accordingly, with respect to RFPs Nos. 2-7, and 9-12, please indicate whether BDSI's production is complete. To the extent BDSI asserts that no responsive documents exist, please so state. Additionally, please provide a date certain for complying with these RFPs.

Finally, to the extent BDSI asserts that any relevant and responsive documents are privileged, please provide the required identification of each such piece of information as explained in Section 1, *supra*.

4. Summary.

We are looking forward to BDSI's supplemented production no later than 14 days from the date of this letter. To the extent BDSI will not comply with any of Aquestive's requests for supplementation, please provide your availability for a meet and confer on either Thursday, October 28 or Friday, October 29.

Regards,

/s/ Anna M Targowska

Anna M Targowska

AMT